SEP - 8 2008

Attachment IV 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is: _____

1. Applicant Device Information

Trade/Proprietary Name: Weigao Disposable Empty Cartridge Syringe
Common Name: Syringe, Piston
Classification Name: Syringe, Piston
Device Class: II
Product Code: FMF
Regulation Number: 880.5860

Intended Use:

Weigao Disposable Empty Cartridge Syringe is intended for use in the withdrawal and administration of fluid in accordance with the best judgment of the physician.

2. Submitter Information

Establishment Registration Name:
ShanDong WeiGao Group Medical Polymer Products Co., LTD
No.312, Shichang Road
Weihai, Shandong,
China, 264209

Contact Person of the Submission:
Ms. Diana Hong;
Mr. Eric Chen
Suite 8D, Zhongxin Zhongshan Mansion,
No.19, Lane 999, South Zhong Shan No.2 Road
Shanghai, China 20020
Phone: +86-21-64264467 x 152
Fax: +86-21-64264468 x 809
Email: Diana.hong@mid-link.net
Eric.chen@mid-link.net

3. Predicate Device

Predicate device
K820164
Trade/Proprietary Name: Empty Sterile Carpuject® Cartridge
Common/Usual Name: Piston syringe.
Classification Name: Syringe, piston

Submitter Name: Hospira, Inc.

Address:
D-389, Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045
Attn: Diane Rennpferd
Phone: (224) 212-5452
Fax: (224) 212-5401

4. Device Description

The subject device of Weigao Disposable Empty Cartridge Syringe is an empty cartridge syringe that consists of a hollow barrel and a movable plunger. The syringes are designed for manual use. The applicant syringe's main components are made of glass.

Specifications:
Model 1 ml Slim with scale marks (fixed with Needle 27G),

The applicant devices don't contain drug or biological products. They are not for life-supporting or life-sustaining. It is not for implant.

No antimicrobial or antithrombotic ingredient is applied on the applicant device.

No chemical for the enhancement of its clinical performance is applied on or incorporated into applicant device.

No specific drug or biologic is applied with the applicant device.

5. Test Data

The biocompatibility tests are conducted following ISO 10993 as **Appendix 1** Biocompatibility

Test.

The performance bench tests follows ISO 11040-4, ISO 7886-1, ISO 9626 are provided as **Appendix 2** Performance Test.

6. Substantially Equivalence

The applicant device is **Substantially Equivalent (SE)** to the predicate device in terms of Effectiveness and Safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2008

ShanDong WeiGao Group Medical Polymer Products Company, Limited
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, Zhongxin Zhongshan Mansion
No. 19, Lane 999, Zhong Shan No. 2 Road(S)
Shanghai
CHINA 200030

Re: K081241
Trade/Device Name: WeiGao Disposable Empty Cartridge Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 28, 2008
Received: July 30, 2008

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:_____

Device Name: Weigao Disposable Empty Cartridge Syringe

Indications for Use:

Weigao Disposable Empty Cartridge Syringe is intended for use in the withdrawal and administration of fluid in accordance with the best judgment of the physician.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K081241